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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,332	04/21/2004	Ana San Gabriel	26099	4229

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NATH & ASSOCIATES
1030 15th STREET, NW
6TH FLOOR
WASHINGTON, DC 20005

EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,332	GABRIEL ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 7-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/21/04 & 2/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 4-6 in the reply filed on 4/26/2005 is acknowledged.

Status of Application, Amendments, And/Or Claims

Claims 1-15 are pending. The amendment of claims 4-9, 11, and 13-15 has been made of record.

Claims 1-3, and 7-15 are withdrawn from further consideration as being drawn to a nonelected Invention.

Claims 4-6 are examined on the merit to the extent that they read on the elected invention.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/JP02/10984, filed 10/23/2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Objections

Claims 4-6 are objected to as being dependent upon a non-elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter.

Claims 4-6 are rejected under 35 U.S.C. 101 because a DNA that encodes a glutamic acid receptor that has (i) a transmembrane domain, (ii) in intracellular domain common to type 4 metabotropic glutamic acid receptor (iii) extracellular domain shorter by about 316 or 327 than type 4 metabotropic glutamic acid receptor, and (iv) a cell harboring the DNA, exists in a cell as product of the nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to a DNA that encodes a glutamic acid receptor that has (i) a transmembrane domain, (ii) in intracellular domain common to type 4 metabotropic glutamic acid receptor (mGluRec), (iii) extracellular domain shorter by about 316 or 327 than type 4 metabotropic glutamic acid receptor, (iv) a cell harboring the DNA, and (v) a method of producing the receptor protein.

The specification must provide sufficient distinguishing identifying characteristics for the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the chemical product, or any combination thereof. In this case, the specification provides support for the expressing a variant glutamic acid receptor by measuring cAMP accumulation (page 30, Example – 4). The specification fails to disclose any conserved domain or specific functional feature of the polypeptide. The instant specification does not provide specific guidance about common intracellular domain of type 4 mGluRec. Further, the specification does not provide any specific guidance on to what residues constitute extracellular domain or intracellular domain of the peptide. In the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed invention.

This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description"

Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

As discussed above, the skilled artisan cannot envision the detailed structure of the leptin receptor and/or forskolin inducible PAP1 promoter in a reporter construct, and therefore conception is not achieved until reduction to practice has occurred.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA encoding for a glutamic acid receptor protein of SEQ ID NO: 7, does not reasonably provide enablement for a DNA which encodes any glutamic acid receptor having an intracellular domain common to type 4 m GluRec protein that has an extracellular domain shorter by 316 or 327 amino acid residue to a type 4 GluRec protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to which the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276

(CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

Claims are drawn to a DNA that encodes a glutamic acid receptor that has (i) a transmembrane domain, (ii) in intracellular domain common to type 4 metabotropic glutamic acid receptor (mGluRec), (iii) extracellular domain shorter by about 316 or 327 than type 4 metabotropic glutamic acid receptor, (iv) a cell harboring the DNA, and (v) a method of producing the receptor protein.

The instant specification discloses identification of a glutamic acid receptor of SEQ ID NO: 6 comprising 584 amino acids. The specification discloses that the polypeptide is expressed in goblet cell and is functionally related to secretion of mucoid (page 28, 2nd paragraph). The instant specification does not disclose any consensus

sequence to which one skill in the art can compare the polypeptide. Based on the homology of claimed novel mGluRec variant, Applicant assumes that the variant mGluRec should have function similar to other known Glutamic acid receptors. The specification does not provide specific guidance about common intracellular domain of type 4 mGluRec. Further, the specification does not provide any specific guidance on to what residues constitute extracellular domain or intracellular domain of the peptide. Therefore, it will require undue experimentation to identify all the glutamic acid receptors and its variants including including substitutions, insertions or deletion to the polypeptide with (i) a transmembrane domain, (ii) in intracellular domain common to type 4 metabotropic glutamic acid receptor (mGluRec), (iii) extracellular domain shorter by about 316 or 327 than type 4 metabotropic glutamic acid receptor.

Because the claims encompass a polynucleotide that encodes a glutamic acid receptor that has (i) a transmembrane domain, (ii) in intracellular domain common to type 4 metabotropic glutamic acid receptor (mGluRec), (iii) extracellular domain shorter by about 316 or 327 than type 4 metabotropic glutamic acid receptor, (iv) a cell harboring the DNA, and (v) a method of producing the receptor protein, in the light of the teachings of the unpredictability found in the art discussed and because of the supra lack of sufficient teachings in applicants disclosure to overcome those teachings, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 4-6 which depend from claim 1, the term "an extracellular domain by about 316 or 327 amino acid shorter than that of the type 4 metabotropic glutamic acid receptor protein" renders the claim indefinite because the specification compares with mGluR4 of O'Hara et al Neuron, 11: 42, 1993 (page 12, 2nd paragraph). However, at least 8 different metabotrophic Glutamic acid receptor proteins have been reported to exist, and claims are not limited only to a particular sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaudhari et al. (IDS, Nature neurosci. 3: 113-119, 2000).

Claims are drawn to a DNA that encodes a glutamic acid receptor that has (i) a transmembrane domain, (ii) in intracellular domain common to type 4 metabotropic

glutamic acid receptor (iii) extracellular domain shorter by about 316 or 327 than type 4 metabotropic glutamic acid receptor, (iv) a cell harboring the DNA, and (v) a method of producing the receptor protein.

Chaudhari et al. (2000) teach identifying a metabotropic glutamate receptor variant that has a transmembrane, an intracellular domain common to type 4 metabotropic receptor, a shorter receptor than a type 4 metabotropic receptor, and a method of expressing the receptor in CHO cells (pages 114, right column through 117). They teach that the first ~60 bp of the receptor is unique and rest of at least 2220 bps are identical to metabotropic glutamic acid receptor from brain. They teach that the protein is a mature form and plays role in taste recognition (page 116, 2nd paragraph of the right column). Chaudhari el al also suggest for the presence of other splice variants of taste- mGluR4 mRNA as multiple promoters may yield mRNAs with distinct 5' exons (pg 118, last paragraph of the left column). Thus, it meets the limitations of claimed invention of a taste mGluRec, which is shorter than mGluRec4 by about 316 or 327.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
28 June 2005

JANET ANDRES
PRIMARY EXAMINER